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ATTORNEY'S DOCKET NO: B0801/7202 (AWS)

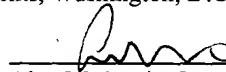
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Weiner et al.
Serial No: 09/809,745
Filed: March 15, 2001
For: SUPPRESSION OF VASCULAR DISORDERS BY MUCOSAL
ADMINISTRATION OF HEAT SHOCK PROTEIN PEPTIDES

Examiner: Unknown
Art Unit: Unknown

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, Washington, D.C. 20231, on the 6th day of June, 2001.


Alan W. Steele, Reg. No.: 45,128

Commissioner for Patents
Washington, D.C. 20231

Sir:


Transmitted herewith are the following documents:

- ☒ Information Disclosure Statement with References Cited
- ☒ Form PTO-1449
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617)720-3500, Boston, Massachusetts.

If a fee is determined to be required, please charge the fee to the account of the undersigned, Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,
Weiner et al., Applicants

By: 
Alan W. Steele, Reg. No. 45,128
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, MA 02210
Telephone (617) 720-3500

Docket No. B0801/7202 (AWS)
Dated: June 6, 2001



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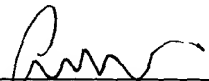
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Commissioner for Patents
Washington, D.C. 20231

**STATEMENT FILED PURSUANT TO THE DUTY OF
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

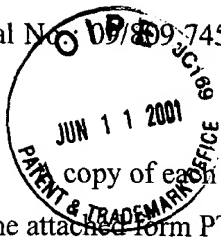
Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed within three months of the filing date of a National Application and before the mailing date of a first Office Action on the merits in the above-identified case. No fee or certification is required.

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.



PART III: Remarks

copy of each of the above-identified information is enclosed unless otherwise indicated on the attached form PTO-1449 (modified). It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

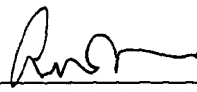
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

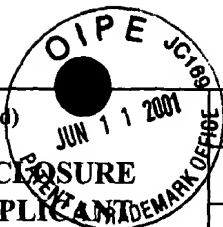
Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,
Weiner et al., Applicants

By: 
Alan W. Steele, Reg. No. 45,128
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600 Atlantic Avenue
Boston, MA 02210
Telephone (617) 720-3500

Docket No. B0801/7202 (AWS)
Dated: June 6, 2001
X June 15, 2001



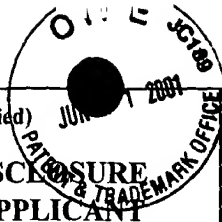
FORM PTO-1449/A and B (Modified)		APPLICATION NO.: 09/809,745	ATTY. DOCKET NO.: B0801/7202
INFORMATION DISCLOSURE STATEMENT BY APPLICANT		FILING DATE: March 15, 2001	
		APPLICANT: Weiner et al.	
Sheet	1	of	4
		GROUP ART UNIT: unknown	EXAMINER: unknown

U.S. PATENT DOCUMENTS

Examiner's Initials#	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	3,561,444		Boucher	02-09-1971
	A2	3,699,963		Zaffaroni	10-24-1972
	A3	3,703,173		Dixon	11-21-1972
	A4	3,944,064		Bashaw et al.	03-16-1976
	A5	3,948,262		Zaffaroni	04-06-1976
	A6	3,993,073		Zaffaroni	11-23-1976
	A7	4,226,848		Nagai et al.	10-07-1980
	A8	4,309,404		DeNeale et al.	01-05-1982
	A9	4,309,406		Guley et al.	01-05-1982
	A10	4,556,552		Porter et al.	12-03-1985
	A11	4,624,251		Miller	11-25-1986
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	A13	4,675,189		Kent et al.	06-23-1987
	A14	4,704,295		Porter et al.	11-03-1987
	A15	4,713,243		Schiraldi et al.	12-15-1987
	A16	4,837,027		Lee et al.	06-06-1989
	A17	4,895,724		Cardinal et al.	01-23-1990
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	A19	4,940,587		Jenkins et al.	07-10-1990
	A20	4,985,253		Fujioka et al.	01-15-1991
	A21	5,110,597		Wong et al.	05-05-1992
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	A32	5,840,855		Shinnick et al.	11-24-1998
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	A34	5,869,054		Weiner et al.	02-09-1999
	A35	5,869,093		Weiner et al.	02-09-1999
	A36	5,961,977		Hafler et al.	10-05-1999

FOREIGN PATENT DOCUMENTS

Examiner's Initials#	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B1	EPO	EP 205282	B1		09-13-1995	
	B2	EPO	EP 259013	B1		06-05-1991	

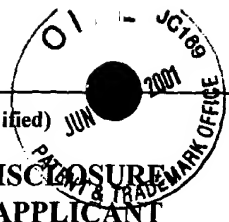


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	B3	EPO	EP 354742	B1		03-16-1994	
	B4	EPO	EP 516141	B1		08-14-1996	
	B5	WIPO	WO85/02092	A1		05-23-1985	
	B6	WIPO	WO88/10120	A1		12-29-1988	
	B7	WIPO	WO91/01333	A1		02-07-1991	
	B8	WIPO	WO95/11011	A1		04-27-1995	
	B9	WIPO	WO95/15191	A1		06-08-1995	
	B10	WIPO	WO95/27499	A1		10-19-1995	
	B11	WIPO	WO95/27500	A1		10-19-1995	
	B12	WIPO	WO00/20019	A2		04/13/2000	

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials#	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	AFEK A et al., Immunization of low-density lipoprotein receptor deficient (LDL-RD) mice with heat shock protein 65 (HSP-65) promotes early atherosclerosis. <i>J Autoimmun.</i> 2000 Mar;14(2):115-21.	
	C2	DAHIYAT BI et al., De novo protein design: fully automated sequence selection. <i>Science.</i> 1997 Oct 3;278(5335):82-7.	
	C3	GEORGE J et al., Enhanced fatty streak formation in C57BL/6J mice by immunization with heat shock protein-65. <i>Arterioscler Thromb Vasc Biol.</i> 1999 Mar;19(3):505-10.	
	C4	GEORGE J et al., Requisite role for interleukin-4 in the acceleration of fatty streaks induced by heat shock protein 65 or Mycobacterium tuberculosis. <i>Circ Res.</i> 2000 Jun 23;86(12):1203-10.	
	C5	HUNTER et al., The gastric emptying of hard gelatin capsules. <i>Int J Pharmaceutics.</i> 1983; 17:59-64.	
	C6	JINDAL S et al., Primary structure of a human mitochondrial protein homologous to the bacterial and plant chaperonins and to the 65-kilodalton mycobacterial antigen. <i>Mol Cell Biol.</i> 1989 May;9(5):2279-83.	
	C7	KALMAN S et al., Comparative genomes of Chlamydia pneumoniae and C. trachomatis. <i>Nat Genet.</i> 1999 Apr;21(4):385-9.	
	C8	KAUFMANN SH, Heat shock proteins and the immune response. <i>Immunol Today.</i> 1990 Apr;11(4):129-36.	
	C9	KEREN P et al., Effect of hyperglycemia and hyperlipidemia on atherosclerosis in LDL receptor-deficient mice: establishment of a combined model and association with heat shock protein 65 immunity. <i>Diabetes.</i> 2000 Jun;49(6):1064-9.	
	C10	KIKUTA LC et al., Isolation and sequence analysis of the Chlamydia pneumoniae GroE operon. <i>Infect Immun.</i> 1991 Dec;59(12):4665-9.	
	C11	KOL A et al., Chlamydial and human heat shock protein 60s activate human vascular endothelium, smooth muscle cells, and macrophages. <i>J Clin Invest.</i> 1999 Feb;103(4):571-7.	
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	C14	LINDQUIST S, The heat-shock response. <i>Annu Rev Biochem.</i> 1986;55:1151-91.	
	C15	MACH F et al., Reduction of atherosclerosis in mice by inhibition of CD40 signalling. <i>Nature.</i> 1998 Jul 9;394(6689):200-3.	
	C16	MARON R et al., Mucosal administration of HSP 65 decreases atherosclerosis and inflammation in the aortic arch of LDL receptor deficient mice. AAI/CIS Joint Annual Meeting, Seattle, WA, 12-16 May 2000; <i>FASEB J.</i> 2000 Apr 20;14(6):A1199. (ABSTRACT No. 183.9).	



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C17	MERRIFIELD RB, Peptide synthesis on a solid polymer. <i>Fed Proc Am Soc Exp Biol.</i> 1962;21:412 (ABSTRACT).		
C18	MERRIFIELD RB, Solid phase peptide synthesis. I. The synthesis of a tetrapeptide. <i>J Am Chem Soc.</i> 1963 Jul 20; 85:2149-54.		
C19	METZLER B et al., Inhibition of arteriosclerosis by T-cell depletion in normocholesterolemic rabbits immunized with heat shock protein 65. <i>Arterioscler Thromb Vasc Biol.</i> 1999 Aug;19(8):1905-11.		
C20	MITCHELL AR et al., tert-Butoxycarbonylaminoacyl-4-(oxymethyl)-phenylacetamidomethyl-resin, a more acid-resistant support for solid-phase peptide synthesis. <i>J Am Chem Soc.</i> 1976 Nov 10;98(23):7357-62.		
C21	MORIMOTO RI, Heat shock: the role of transient inducible responses in cell damage, transformation, and differentiation. <i>Cancer Cells.</i> 1991 Aug;3(8):295-301.		
C22	NICOLETTI A et al., Immunomodulation of atherosclerosis: myth and reality. <i>J Intern Med.</i> 2000 Mar;247(3):397-405.		
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C24	PELHAM HR, Heat shock and the sorting of luminal ER proteins. <i>EMBO J.</i> 1989 Nov;8(11):3171-6.		
C25	PELHAM HR, Speculations on the functions of the major heat shock and glucose-regulated proteins. <i>Cell.</i> 1986 Sep 26;46(7):959-61.		
C26	QIAO JH et al., Pathology of atheromatous lesions in inbred and genetically engineered mice. Genetic determination of arterial calcification. <i>Arterioscler Thromb.</i> 1994 Sep;14(9):1480-97.		
C27	SHINNICK TM, The 65-kilodalton antigen of Mycobacterium tuberculosis. <i>J Bacteriol.</i> 1987 Mar;169(3):1080-8.		
C28	SHOENFELD Y et al., Atherosclerosis as an infectious, inflammatory and autoimmune disease. <i>Trends Immunol.</i> 2001 Jun;22(6):293-5.		
C29	SHOENFELD Y et al., Heat shock protein 60/65, beta 2-glycoprotein I and oxidized LDL as players in murine atherosclerosis. <i>J Autoimmun.</i> 2000 Sep;15(2):199-202.		
C30	SMART JD et al., An in-vitro investigation of mucosa-adhesive materials for use in controlled drug delivery. <i>J Pharm Pharmacol.</i> 1984 May;36(5):295-9.		
C31	THOLE JE et al., Characterization, sequence determination, and immunogenicity of a 64-kilodalton protein of Mycobacterium bovis BCG expressed in escherichia coli K-12. <i>Infect Immun.</i> 1987 Jun;55(6):1466-75.		
C32	WICK G et al., Role of heat shock protein 65/60 in the pathogenesis of atherosclerosis. <i>Int Arch Allergy Immunol.</i> 1995 May-Jun;107(1-3):130-1.		
C33	XU Q et al., Increased expression of heat shock protein 65 coincides with a population of infiltrating T lymphocytes in atherosclerotic lesions of rabbits specifically responding to heat shock protein 65. <i>J Clin Invest.</i> 1993 Jun;91(6):2693-702.		
C34	XU Q et al., Induction of arteriosclerosis in normocholesterolemic rabbits by immunization with heat shock protein 65. <i>Arterioscler Thromb.</i> 1992 Jul;12(7):789-99.		
C35	XU Q et al., Regression of arteriosclerotic lesions induced by immunization with heat shock protein 65-containing material in normocholesterolemic, but not hypercholesterolemic, rabbits. <i>Atherosclerosis.</i> 1996 Jun;123(1-2):145-55.		
C36	YUAN Y et al., Monoclonal antibodies define genus-specific, species-specific, and cross-reactive epitopes of the chlamydial 60-kilodalton heat shock protein (hsp60): specific immunodetection and purification of chlamydial hsp60. <i>Infect Immun.</i> 1992 Jun;60(6):2288-96.		

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Sheet	4	of	4		

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. _____, filed _____, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

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